In the Claims

Claims 1 to 64 (Cancelled)

65. (Original) A pharmaceutical product comprising:

(i) a pressurized MDI (metered dose inhaler) container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the group consisting of HFA 134a and HFA p227, or a mixture thereof;

(ii) an effective amount of an HFA adsorbent material; and

(iii) a sealed package having an enclosed volume within which the pressurized container and the HFA adsorbent material are situated,

wherein the sealed package is impermeable to the HFA propellant and the pressure within the enclosed volume of the package is equal to about ambient pressure; and wherein the HFA adsorbent material is capable of adsorbing the HFA propellant so as to maintain a constant pressure within said enclosed volume, when any leakage of the HFA propellant occurs from the pressurized container.

66. (Original) The pharmaceutical product according to claim 65, wherein the drug is selected from the group consisting of bronchodilators, antihistamines, lung surfactants, antiviral agents, corticosteroids, ant-inflammatory agents, anti-cholinergics, and antibiotics.

67. (Original) The pharmaceutical product according to claim 65, wherein the pressurized MDI (metered dose inhaler) container further comprises one or more excipients selected from the group consisting of surfactants, preservatives, flavorings, antioxidants, anti-aggregating agents and co-solvents.

68. (Original) The pharmaceutical product according to claim 65, wherein the HFA propellant is HFA 134a.

69. (Original) The pharmaceutical product according to claim 65, wherein the HFA propellant is HFA p227.

70. (Original) The pharmaceutical product according to claim 65, wherein the HFA adsorbent material is capable of adsorbing the HFA propellant up to about 25% of the weight of the adsorbent.

71. (Original) The pharmaceutical product according to claim 65, wherein the HFA gas adsorbent material is capable of adsorbing the HFA propellant up about 20% of the weight of the adsorbent.

72. (Original) The pharmaceutical product according to claim 65, wherein the HFA adsorbent material comprises material selected from the group consisting of molecular sieves, activated clays, activated alumina, silica, zeolites, bauxites, and mixtures thereof.
73. (Original) The pharmaceutical product according to claim 72, wherein the HFA adsorbent material is 10 Å (Angstrom) molecular sieves.
74. (Original) The pharmaceutical product according to claim 73, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA p227.
75. (Original) The pharmaceutical product according to claim 73, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA 134a.
76. (Original) The pharmaceutical product according to claim 65, wherein the package is impermeable to HFA 134a.
77. (Original) The pharmaceutical product according to claim 65, wherein the package is impermeable to HFA p227.
78. (Original) The pharmaceutical product according to claim 65, wherein the package is made of metal, glass, or plastic, and is selected from the group consisting of bottles, bags, drum boxes, and irregularly shaped containers.
79. (Original) The pharmaceutical product according to claim 78, wherein the package is made of plastic.
80. (Original) The pharmaceutical product according to claim 79, wherein the plastic is a flexible laminate having a barrier layer providing said package with impermeability to HFA 134a and/or HFA p227.
81. (Original) The pharmaceutical product according to claim 80, wherein said flexible laminate has three layers: polyester / aluminum / polyethylene, wherein the aluminum layer is between the polyester and polyethylene layers.
82. (Original) The pharmaceutical product according to claim 80, wherein said barrier layer is made of aluminum foil.
83. (Original) The pharmaceutical product according to claim 65, wherein the sealed package is hermetically sealed by heat-sealing, gluing, welding, brazing, mechanical closures or clamps, or compression.

Claims 84 to 108 (Cancelled)

109. (New) A method for maintaining the enclosed volume of a sealed package at about ambient pressure, wherein the package contains pressurized MDI (metered dose inhaler)

container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the group consisting of HFA 134a and HFA p227, or a mixture thereof; wherein the method comprises the steps of:
(i) positioning an effective amount of a HFA adsorbent material, and said pressurized container, within a sealable package;
(ii) sealing the package so that the pressurized container and adsorbent are in an enclosed volume within the package at a pressure equal to about ambient pressure; and
(iii) adsorbing any leakage of the HFA propellant into the HFA adsorbent material so as to maintain the enclosed volume at about ambient pressure;
wherein the HFA adsorbent material is 10 Å (Angstrom) molecular sieves.

110. (New) The method according to claim 109, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA p227.

111. (New) The method according to claim 109, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA 134a.

112. (New) A method for maintaining the enclosed volume of a sealed package at about ambient pressure, wherein the package contains pressurized MDI (metered dose inhaler) container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the group consisting of HFA 134a and HFA p227, or a mixture thereof; wherein the method comprises the steps of:
(i) positioning an effective amount of a HFA adsorbent material, and said pressurized container, within a sealable package;
(ii) sealing the package so that the pressurized container and adsorbent are in an enclosed volume within the package at a pressure equal to about ambient pressure; and
(iii) adsorbing any leakage of the HFA propellant into the HFA adsorbent material so as to maintain the enclosed volume at about ambient pressure;
wherein the package is impermeable to HFA 134a.

113. (New) A method for maintaining the enclosed volume of a sealed package at about ambient pressure, wherein the package contains pressurized MDI (metered dose inhaler) container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the

group consisting of HFA 134a and HFA p227, or a mixture thereof; wherein the method comprises the steps of:
(i) positioning an effective amount of a HFA adsorbent material, and said pressurized container, within a sealable package;
(ii) sealing the package so that the pressurized container and adsorbent are in an enclosed volume within the package at a pressure equal to about ambient pressure; and
(iii) adsorbing any leakage of the HFA propellant into the HFA adsorbent material so as to maintain the enclosed volume at about ambient pressure;
wherein the package is impermeable to HFA p227.

114. (New) A method for maintaining the enclosed volume of a sealed package at about ambient pressure, wherein the package contains pressurized MDI (metered dose inhaler) container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the group consisting of HFA 134a and HFA p227, or a mixture thereof; wherein the method comprises the steps of:
(i) positioning an effective amount of a HFA adsorbent material, and said pressurized container, within a sealable package;
(ii) sealing the package so that the pressurized container and adsorbent are in an enclosed volume within the package at a pressure equal to about ambient pressure; and
(iii) adsorbing any leakage of the HFA propellant into the HFA adsorbent material so as to maintain the enclosed volume at about ambient pressure; wherein
the package is made of plastic and wherein the plastic is a flexible laminate having a barrier layer providing said package with impermeability to HFA 134a and/or HFA p227.

115. (New) The method according to claim 114, wherein said flexible laminate has three layers: polyester/aluminum/polyethylene, wherein the aluminum layer is between the polyester and polyethylene layers.

116. (New) The method according to claim 114, wherein said barrier layer is made of aluminum foil.

117. (New) A pharmaceutical product comprising:

(i) a pressurized MDI (metered dose inhaler) container comprising a drug, and an HFA (hydrofluoroalkane) propellant selected from the group consisting of HFA 134a and HFA p227, or a mixture thereof;

(ii) an effective amount of an HFA adsorbent material; and

(iii) a sealed package having an enclosed volume within which the pressurized container and the HFA adsorbent material are situated,

wherein the pressure within the enclosed volume of the package is equal to about ambient pressure;

wherein the HFA adsorbent material is capable of adsorbing the HFA propellant so as to maintain a constant pressure within said enclosed volume, when any leakage of the HFA propellant occurs from the pressurized container; and

wherein the package has a permeability to HFA p227 that is less than or equal to about 0.25 cc of HFA p227 per square meter of package per day at about 1 bar pressure and about room temperature, or a permeability to HFA 134a that is less than or equal to about 4.1 cc of HFA 134a per square meter of package per day at about 1 bar pressure and about room temperature; wherein

the HFA adsorbent material is 10 Å molecular sieves.

118. (New) A pharmaceutical product according to claim 117, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA p227.

119. (New) A pharmaceutical product according to claim 117, wherein the molecular sieves, in an amount of about 4 grams, absorbs about 230 ml of HFA 134a.

Discussion of the Amendment to the Claims

Claims 1 to 64, and claims 84 to 108 have been cancelled, without prejudice. Applicant reserves the right to pursue the subject matter of cancelled claims 1 to 64, and of cancelled claims 84 to 108 in pending or subsequently filed continuation, continuation-in-part, or divisional applications.

Claims 65 to 83, as originally presented, remain pending in this application.

New claim 109 recites the subject matter of cancelled claim 9, in an independent format.

New claims 110 and 111 recite the subject matters of cancelled claims 10 and 11, respectively, and are dependent on new claim 109.

New claim 112 recites the subject matter of cancelled claim 12 in an independent format.

New claim 113 recites the subject matter of cancelled claim 13 in an independent format.

New claim 114 recites the subject matter of cancelled claim 29 in an independent format.

New claims 115 and 116 recite the subject matters of cancelled claims 30 and 31, respectively, and are now dependent on new claim 114.

New claim 117 recites the subject matter of cancelled claim 100 in an independent format.

New claims 118 and 119 recite the subject matter of cancelled claims 101 and 102, respectively, and are now dependent on new claim 117.

Accordingly, these amendments to the claims add no new matter.

As presently amended, claims 65 to 83, and claims 109 to 119 are pending in this application.

Discussion of the Allowed Claims

Applicant notes with appreciation, the Examiner's indication that claims 65 to 83 are allowable. (Office Action at 5).

Discussion of the Claims That are Objected To

Applicant notes with appreciation, the Examiner's indication that claims 9 to 13, 29 to 31 and 100 to 102 would be allowable if amended to include all of the limitations of the base claim and any intervening claim. (Office Action at 5).

With the present amendment, new claims 109 to 113, 114 to 116, and 117 to 119, recite the subject matters of original claims 9 to 13, 29 to 31 and 100 to 102, respectively, as amended to comply with the Examiner's requirements, rendering the Examiner's objections to these claims moot.

Accordingly, reconsideration and withdrawal of the objection to the corresponding new claims are respectfully requested.

Discussion of the Rejections of Claims

Claims 33 to 64 stand rejected under 35 U.S.C. § 101 as, the Examiner alleges, being drawn to non-statutory subject matter. (Office Action at 2).

Claims 1 to 8, 14, 19, 26 to 28, 32 to 40, 46, 51, 58, 59, 61 and 64 stand rejected under 35 U.S.C. § 102(b) as, the Examiner alleges, being anticipated by Garrill et al. (6, 179, 118 B1). (Office Action at 3).

Claims 15 to 18, 20 to 25, 47 to 50, 52 to 57, 84 to 99, and 103 to 108 stand rejected under 35 U.S.C. § 103(a) as, the Examiner alleges, being unpatentable over Garrill et al. (Office Action at 4).

As discussed above, claims 1 to 64, and claims 84 to 108 have been cancelled, without prejudice. Meanwhile, the subject matters of the rejected claims 1 to 8, 14 to 28, 32 to 64, 84 to 99, and 103 to 108 do not appear in any original or new claim of this application as presently amended.

Accordingly, the Examiner's rejections of these claims under 35 U.S.C. §§ 101, 102 and 103 are rendered moot.

In view of the present amendment and remarks, Applicants submit that the invention as defined by the claims of the present application is novel and non-obvious over the prior art, and complies with the provisions of 35 U.S.C. § 112. Therefore, allowance and passage to issue of Claims 65 to 83 and 109 to 119 are respectfully requested.

Respectfully submitted,

Dated: November 22, 2005

Paul R. Darkes, Reg. No., 33,862
Attorney for Applicants

Aventis Pharmaceuticals Inc.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, New Jersey 08807-0800
Telephone: 610-889-8458
Telefax: 908-231-2626

Docket No. USAV 2001/0077 US NP